EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-CV-12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris**

DEY DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE EVIDENCE OF GOVERNMENT KNOWLEDGE

PRELIMINARY STATEMENT

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") submit this memorandum of law in opposition to the United States' Motion *in Limine* to Preclude Evidence of Government Knowledge.

The Government has made a sweeping motion to preclude all so-called government knowledge evidence. The Government does not define or identify the government knowledge evidence it seeks to preclude and Dey and the Court are left guessing as to what exactly the Government means. The Government merely points to six examples of OIG reports and vaguely refers to testimony of former HHS employees who considered AWP a "list price", without identifying the witnesses or the page and line numbers of the depositions. A motion *in limine* must identify the evidence and provide a basis for why each piece of evidence should be excluded. *See, e.g., Veteran Med. Prods., Inc. v. Bionix Dev. Corp.*, No. 1:05-cv-655, 2008 WL 1745586, at *1-2 (W.D. Mich. Apr. 11, 2008). The Government's motion fails to do this and

should be denied on that basis alone.

The Government also is wrong on the law pertaining to government knowledge and makes repeated misstatements of Dey's defense and how government knowledge is part of that defense. Dey's defense is not that its AWPs were "fraudulent" but that the fraud is somehow excused because the Government knew about it. Dey's defense is that there was no fraud and there were no false claims submitted to the federal government that were based on allegedly false statements made by Dey. Dey published AWPs that it believed were proper and appropriate in light of what Dey believed about the industry at the time. Government knowledge evidence, therefore, is relevant to Dey's defense under the federal False Claims Act ("FCA") because it will show Dey's actions were reasonable and not misleading in light of what was known at the time. The evidence is relevant and indeed indispensable to resolving the elements of "falsity" and "scienter." In this case, that means the Government must show that Dey knew the Government was unintentionally overpaying claims. This Court has already held evidence of what the Government knows is relevant for these purposes. *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 140, 148-149, 152 (D. Mass. 2008); *In re Pharm. Indus. Average Wholesale Price Litig. (California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs., Inc.)*, 478 F. Supp. 2d 164, 172, 174 (D. Mass. 2007).

The element of "falsity" under the FCA can only be evaluated by an objective standard. *See, e.g., United States v. Prabhu*, 442 F. Supp. 2d 1008, 1032-33 (D. Nev. 2006). Government knowledge evidence demonstrates that there was no universally accepted objective standard defining AWP at the time Dey set its AWPs for the subject inhalation drugs in 1992, 1996 and 1997, that Dey set its AWPs in a manner that it believed was well within the bounds of generic industry practice at the time, and that no reasonable person would have thought Dey's

AWPs were false in light of what was known at the time. Evidence will also show that the Government had the "true" prices for Dey's drugs that it now claims it did not know about.

As this Court has held, when the Government's knowledge is "extensive", the defendant cannot possess the requisite scienter under the FCA. *Mylan Labs.*, 608 F. Supp. 2d at 149. Indeed, courts have found that precisely the type of evidence the Government seeks to exclude here, such as testimony from CMS Administrators and OIG reports, is relevant to a government knowledge defense. *See id*. at 150; *United States ex rel. Englund v. Los Angeles County*, No. Civ. S-04-282 LKK/JFM, 2006 WL 3097941, at *13-14 (E.D. Cal. Oct. 31, 2006). The evidence also demonstrates an almost universal understanding within the pharmaceutical industry that AWPs did not represent – and were not intended to represent – providers' net discounted prices, which demonstrates that Dey acted in a manner consistent with what it believed industry practice to be and could not have knowingly caused the submission of a false claim for payment.

The core of the Government's case is that Dey caused it to overpay on each of the claims at issue. The government knowledge evidence is directly relevant to, and indeed refutes, this allegation. To begin with, Dey never submitted any claims for payments to Medicare. The claims for payment were submitted by providers. The claims that were submitted by providers, moreover, do not contain any false statement by Dey or anyone; Dey's AWPs do not even appear anywhere on the claims. Nor did the Government refer to Dey's AWPs when it decided whether to pay the claims. Instead, the Government argues that Dey caused the Government to pay the providers more than it intended because the Government, through its agent DMERCs, in some instances, elected to include publicly reported Dey AWPs as part of its Medicare arrays constructed for median payments for generic drugs. The construction of these arrays by the

agent DMERCs was not transparent to the industry and was done without any input from Dey. This novel attempt to expand the FCA beyond its literal requirement that the Government prove a false claim was presented requires that the Government prove Dey caused it to rely on misinformation. Government knowledge evidence is, therefore, directly relevant to the "causation" element here because it will demonstrate that the Government knew that it was not paying providers based on net acquisition costs, and intended to pay exactly what it did. Dey's reported AWPs, therefore, did not cause the Government to overpay claims.

The government knowledge evidence is also relevant and inseparable from the evidence showing how and why the Government paid the dispensing fee portion of the claims at issue. The evidence will show that, when the Government started reimbursing Dey drugs at fully discounted net prices, it was compelled to increase dispensing fees six-fold. This also is directly relevant to the measure of damages the Government allegedly suffered as a result of the allegedly "false claims" at issue. The total amount of reimbursement for a claim – including both the ingredient cost portion and the dispensing fee portion – the Government paid after adopting Average Sales Price ("ASP") is the best measure of the actual value of the goods and services that were the subject of the allegedly false claims, and, therefore, the best measure of the Government's alleged damages.

Since the very beginning of these so-called AWP cases, the Government has pursued a litigation strategy aimed at eliminating the evidence that most directly refutes their allegations. The Government exploited a nine-year seal period in this action to gain an unfair tactical advantage over Dey, by taking one-sided discovery without giving Dey any reciprocity. This prevented Dey from taking contemporary testimony from responsible officials with fresh recollections. The Government also hid behind *Touhy* regulations to prevent defendants from

taking full discovery of CMS during the MDL class action cases, all the while knowing that the discovery would be inevitable when it would unseal its actions making virtually the same allegations against some of the same defendants. If it had not invoked the *Touhy* regulations, the testimony of long-time CMS Medicare employees might well have made a difference to this Court's view on these cases. For example, Robert Niemann, a policy analyst described by his CMS superiors as the most knowledgeable about Medicare reimbursement, testified that AWP was a "term of art" in the industry as opposed to the plain meaning of the words "average", "wholesale" or "price." *See* pp. 18-19, *infra*.

As a consequence, the prior AWP decisions that the Government argues preclude Dey from presenting its case here were all decided on an incomplete record; defendants were predictably told by the courts that their defenses failed due to insufficient evidence. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 677 (D. Mass. 2006); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009). Then, the Government's cases were finally unsealed as to Abbott, Dey and Roxane against the backdrop of unfavorable rulings resulting from an incomplete record. Now that it has become obvious that the Government's own top officials and internal experts understood AWP the same way drug manufacturers did, and will not be able to withstand cross-examination, the Government seeks to once again obstruct the fact-finder from making an informed decision based on the evidentiary record – the whole record.

ARGUMENT

I. THE GOVERNMENT'S MOTION *IN LIMINE* FAILS BECAUSE IT DOES NOT SPECIFY THE GOVERNMENT KNOWLEDGE IT SEEKS TO PRECLUDE

The Government's motion *in limine* should be denied because it fails to specifically identify what evidence is covered under the amorphous term "government

knowledge." As the moving party, the Government bears the burden of establishing that the evidence it seeks to preclude is "clearly inadmissible for any purpose." *See Large v. Mobile Tool Int'l, Inc.*, No. 1:02-CV-177, 2008 WL 4238963, at *1 (N.D. Ind. Sept. 10, 2008). Generally describing evidence sought to be excluded, without specifying each document and why each document should be excluded, is inadequate. *See Ramirez v. Puerto Rico Power Auth.*, Civil No. 04-2186(SEC), 2007 WL 2768687, at *11 (D.P.R. Sept. 20, 2007) (denying motion as to evidence not specifically identified, but only generally described); *see also Mobile Tool Int'l, Inc.*, 2008 WL 4238963, at *2 (court held that party's failure to identify any specific evidence it wanted excluded from trial "render[ed] it impossible to determine whether [the] evidence was admissible"); *Hillard v. City of Chicago, Ill.*, Civil Action No. 09 C 2017, 2010 WL 1664941, at *2 (N.D. Ill. Apr. 23, 2010) (denying plaintiff's motion *in limine* because it failed to specify the evidence it sought to exclude); *Veteran Med. Prods., Inc.*, 2008 WL 1745586, at *1-2 (denying motion *in limine* where the plaintiffs failed to identify the specific evidence or testimony sought to be excluded, stating that it "[would] not issue a blanket exclusion").

The Government falls far short of meeting its burden. Aside from pointing to six OIG reports as examples of the government knowledge evidence (*see* Dkt. 7132 ("Pl. Mem.") at 3), the Government fails to identify the particular government knowledge evidence it seeks to exclude, and simply asks the Court to issue a "blanket exclusion" for *any* government knowledge evidence. The Government provides no argument for why any of these documents or testimony should be excluded. For this reason alone, the Government's motion should be denied.

II. THE GOVERNMENT'S KNOWLEDGE OF AWP PRICING IS RELEVANT AND ADMISSIBLE

A. This Court Has Already Held That Government Knowledge Is Relevant To Claims Under the False Claims Act

In *Massachusetts v. Mylan Labs.*, this Court held: "Government knowledge could

conceivably be relevant to two elements of the False Claims Act: the falsity of the claim and the defendant's state of mind." 608 F. Supp. 2d at 140, 148-149. This Court further held that, based on the knowledge the Commonwealth gained from a 2002 OIG report, "a government knowledge defense is viable." *See id*. at 152; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d at 172, 174.

The Government does not precisely identify which trial exhibits or testimony it seeks to exclude from evidence, let alone provide an explanation for why the evidence of each does not fall within the Court's prior determination of relevancy of government knowledge evidence under the FCA. Moreover, the six OIG reports of government knowledge evidence the Government cites to as examples exemplify why the Government is wrong. OIG reports are precisely the type of documents this Court has previously held to support a "viable" government knowledge defense. *See Mylan Labs.*, 608 F. Supp. 2d at 150, 152. Continued use of the published AWPs after receiving a report from the OIG showing that AWP exceeded acquisition cost creates a viable government knowledge defense because the Government continued to use the AWPs "as a policy matter." *See id*. at 152.

B. The OIG Reports Are Relevant Evidence Of What Was Occurring in the Market

As one example of government knowledge evidence, the Government points to the 1997 OIG report, "Excessive Medicare Payments for Prescription Drugs." (*See* Dkt. 6184 (Reid Declaration in Support of Dey's Partial Summary Judgment Motion), Ex. 50.) The report focuses on 22 HCPCS codes relating to the top drugs dispensed under the Medicare program, including albuterol sulfate – one of the two Dey drugs at issue here. The OIG found the Medicare reimbursement amount to exceed the "Actual Average Wholesale Price" amount for all 22 of the drugs (and not just Dey's albuterol sulfate), thereby supporting Dey's contention that it

believed the industry-wide practice was not to set AWP at a net discounted price. (*Id*. at page ii.) In response to the report, HCFA admitted: "The published AWPs currently used by Medicare carriers to determine reimbursement do not resemble the actual wholesale prices which are available to the physician and supplier communities that bill for these drugs." (*Id*. at Appendix D, page D-2.) With this knowledge, Congress embraced a policy that continued to pay for albuterol based on AWP instead of net discounted acquisition cost. As HCFA explained to the OIG: "We included a provision in the President's 1998 budget bill that would have eliminated the markup for drugs billed to Medicare by requiring physicians to bill the program the actual acquisition cost for drugs. Unfortunately, this provision was not enacted, but we will pursue this policy in other appropriate ways." (*Id*. at Appendix D, page D-3.)[1]

Despite its knowledge, HCFA chose to direct its agent DMERCs to continue to use published AWPs "as reflected in sources such as the Red Book, Blue Book, or MediSpan," thereby supporting a conscious policy decision, which it renewed each year in subsequent program memoranda. (*See* Dkt. 6184, Ex. 172.) The only time this practice varied was in 2000 when, with the so-called "true" AWP for albuterol sulfate in-hand (*i.e.*, the so-called "DOJ AWP"), CMS issued a program memorandum to the DMERCs stating that they should use them; but, only two months later, due to an uproar from Congress over the possible loss of access for vulnerable patient populations, CMS issued another program memorandum to the DMERCs prohibiting them from using the so-called "true" AWPs. (*See* Dkt. 6190 (Dey's Statement of

[1] These OIG reports are not isolated instances of government knowledge. Dey's trial exhibit list and deposition designations contain an overwhelming amount of evidence, including, *inter alia*: deposition designations from 18 CMS, OIG and Ven-A-Care witnesses; scores of OIG, GAO and other government reports, including 10 reports regarding albuterol sulfate and 4 reports regarding ipratropium bromide; 200+ correspondence among HCFA, Congress, HHS, OIG, Ven-A-Care, and other federal agencies; a dozen HCFA program memoranda; more than 50 letters from Dey to the Government disclosing AMPs and describing AWP; Dey customer contract files produced to the Government; and VA contract files with Dey and Federal Supply Schedule prices.

Facts in Support of Partial Summary Judgment Motion), at ¶¶ 195-198, 202; Dkt. 6184, Exs. 181, 183; July 14, 2010 Declaration of Sarah Reid ("Reid Decl."), Ex. 1 at 183:22-186:11, 246:2-247:12, 263:03-269:01.)

Moreover, government knowledge evidence demonstrates that the Government already had discounted prices it could have used to calculate the so-called "true" AWP. For example, the AWP calculated by the DOJ in 2000 for Dey's albuterol sulfate (NDC 49502069703) was $9.17. (Dkt. 6184, Ex. 181.) At the same time, the Government had Dey's published WAC, which was $7.50, and the AMP Dey reported directly to CMS, which was $5.25. (Dkt. 7126 (Plaintiffs' Motion in Limine to Exclude Certain Testimony of Stiroh), Ex. C (Stiroh Declaration in Support of Dey's Partial Summary Judgment Motion), at Figure E.) CMS, however, continued to direct the DMERCs to use the compendia as the source for AWPs, as opposed to issuing any guidance defining AWP.

C. The Government Misstates the Standard Applicable to the Relevancy of Government Knowledge

The Government's interpretation of the relevancy of government knowledge evidence is based on an overly narrow and incorrect interpretation of the law. First, Plaintiff's contention that so-called government knowledge evidence is relevant to an FCA claim only when it is coupled with some indication of government "approval" is simply wrong. Government approval is not required; acquiescence in a defendant's conduct can preclude FCA liability. *See, e.g., United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 (5th Cir. 2003) (Jones, J., concurring) ("[t]he government's knowledge and acquiescence in its contractor's actions" is "'highly relevant'" to determining FCA liability) (emphasis added). Acquiescence includes "tacit or passive acceptance" and "implied consent." *See* Black's Law Dictionary 26 (9th ed. 2009). Where the Government knew about allegedly fraudulent conduct, and paid

anyway, that defeats FCA liability. *See Englund*, 2006 WL 3097941, at *12 (granting summary judgment for defendants because "the Federal government knew what [defendant] was doing and implicitly approved of [defendant's] actions").[2]

Second, there is no requirement that government knowledge involve direct communications between a defendant and the Government to be relevant. *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) ("[N]either the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference."). In determining that "a government knowledge defense [was] viable" in *Mylan Labs.*, for example, the Court rested its conclusion on a single OIG report. *See* 608 F. Supp. 2d at 150, 152. Nor is there any requirement that the Government explicitly communicate approval to a defendant, let alone that a defendant rely on such explicitly communicated approval. *See, e.g.*, *Englund*, 2006 WL 3097941, at *13-14. In this case, the Government never relied on any discussions with Dey when it decided to use AWP to reimburse for drugs in the first place. Nor did its agent DMERCs ever tell Dey when and if its AWP was included in an array for a particular product. The Government acted on its own understanding obtained independent from Dey. Reports showing what the Government knew are evidence of that understanding.

Dey, moreover, directly told the federal government that AWP did not equal a net average transaction price. For example, starting in 1999, Dey sent letters to DMERCs stating:

> Further, as you also know, the Average Wholesale Price (or "AWP) per unit listed above does <u>not</u> represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to get an AWP before a product is first sold and not

[2] The Government cites to no authority construing the federal FCA, and instead relies on two unpublished decisions from New York and New Jersey state courts construing New York and New Jersey state statutes, respectively. Neither of these decisions is controlling here.

> subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

(*See* Dkt. 6190 at ¶ 149; Dkt. 6184, Ex. 111.) Additionally, beginning at least as early as 1994, Dey's publicly available advertisements stated: "Average wholesale prices do not reflect the actual cost to the pharmacy or the consumer." (*See* Reid Decl., Ex. 2.)

D. Government Knowledge Is Relevant to Falsity

1. Government Knowledge Evidence Demonstrates No Objective Standard to Evaluate "Falsity"

A defendant cannot submit a false claim without objectively violating a "law, regulation, or other source" dictating that the claim is false. *See, e.g.*, *Prabhu*, 442 F. Supp. 2d at 1032-33; *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 828 (W.D. Mich. 2000); *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998). Falsity cannot be established where a defendant's conduct can be reasonably interpreted as authorized under the pertinent statute, regulation, or contract. *See, e.g.*, *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[D]ifferences in interpretation growing out of a disputed legal question are similarly not false under the FCA."); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 771 (N.D. Tex. 2003) ("[T]his evidence shows that it was unclear what products could be billed under code E0277 and that the defendants' use of code E0277 for the ROHO Mattress Overlay was not false or fraudulent …."); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) ("Even viewing Hagood's evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was false within the meaning of the [FCA]").

Additionally, because the FCA is a "quasi-criminal," punitive statute that provides

for automatic trebling, *see, e.g.*, *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-86 (2000), any "doubts about whether the statutory reaches of the FCA can be stretched to implicate [a defendant's] conduct should be construed against the Government[.]" *United States ex rel. Ramadoss v. Caremark Inc.*, 586 F. Supp. 2d 668, 691 (W.D. Tex. 2008).

The Government must show, among other things, that each published AWP was false in comparison to some objective standard. Government knowledge evidence demonstrates that no definition existed for the method by which published AWP for generic drugs should be calculated. Indeed, a government report which presumably the Government seeks to preclude explicitly states that AWP "may be neither 'average' nor 'wholesale'…The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers." (Dkt. 6449 (Torborg Declaration), Ex. 170 (GAO Report, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices"), at 4.)

OIG reports have found various spread differentials between AWP and acquisition cost for generic drugs; some reports have specifically found that there is no meaningful or predictable relationship between AWP and acquisition cost. (*See*, *e.g.*, Dkt. 6184, Exs. 46-55, 60-61.) Likewise, some present and former employees of CMS and OIG have testified about a percentage differential between published AWP and acquisition cost, while others testified that published AWP was meaningless or, as former CMS Administrator Thomas Scully testified, "air." (*See* Dkt. 6447 (Defendants' Combined Statement of Facts Pertinent to the United States' Partial Summary Judgment Motion), at ¶¶ 60-64, 104.) Voluminous other government reports, testimony and other documents demonstrate there was no objective standard to measure a "true" or "false" AWP, and no standard that was conveyed from CMS to Dey. Not even employees of CMS and other federal agencies could agree upon a standard for AWP.

Indeed, the Court's own expert in the MDL class case found that "inconsistent and ambiguous information exists even currently concerning what type of price AWP measures," and that "[t]he continuing confusion is real and understandable." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006). The government knowledge evidence will, therefore, show that there was no objective definition of AWP as a net discounted average of wholesale prices. In fact, in 2003, rather than try to use AWP to obtain actual averages of net discounted transaction prices, Congress scrapped the concept of AWP for Medicare in favor of a defined term – ASP.

2. Government Knowledge Evidence Demonstrates the Government Possessed Knowledge of the True Facts

This Court has held that government knowledge may defeat the element of "falsity" if there is evidence that the Government possessed knowledge of the "true facts." *See Mylan Labs.*, 608 F. Supp. 2d at 148-150. In its motion, the Government attempts to preclude Dey, as a matter of law, from having the opportunity to establish that the Government possessed the "true facts" before the evidence is even presented. This puts the cart before the horse. The Court cannot evaluate whether the defense fails as a matter of law until the evidence has been presented. Indeed, among other things, the OIG prepared reports on Dey's drugs with invoices from pharmacies relating to Dey's drugs, the Government had Dey's net average prices in the form of Average Manufacturer Prices, Ven-A-Care sent the Government wholesaler and GPO prices for Dey's drugs for almost the entire time period, the federal government had Federal Supply Schedule Prices and audited contract prices between Dey and its agencies, and Dey, itself, began producing customer contract files to the Government as early as 1997. (*See* Dkt. 6190 at ¶¶ 89-92, 123-26, 129-30, 132-40, 145-47.)

With all of the so-called "true prices" for Dey's drugs in its possession, CMS

made policy decisions to continue to use Dey's compendia AWPs instead. Indeed, Medicare even prohibited the use of so-called "true" DOJ AWPs for Dey's drugs. (*See* Dkt. 6184, Ex. 183.)

3. The Government's Arguments Are Meritless

The Government argues that Dey's AWPs are "false" because they "did not resemble actual prices." (Pl. Mem. at 4.) That AWP is not a transaction price does not make it a fake price. Dey's AWPs were the real AWPs as Dey believed that term was used and understood in the generic industry and by the Government. Dey set its AWP prices at least 10% below the AWPs for the corresponding brand AWPs and then left them unchanged. (Dkt. 6190 at ¶¶ 66-70.) Since brand drugs are frequently purchased between 20% and 25% below the brand AWP, and brand AWPs may increase over time, purchasers frequently purchase brand drugs at prices above the AWP for the corresponding generic drug. (*See* Dkt. 6914 (United States' Motion to Exclude Certain Opinions of Bradford), Ex. 1 (3/6/09 Bradford Report) at ¶ 89, Figure 11.) Therefore, Dey's AWP for its generic drugs represents a discounted price as compared to the transaction price for the brand drug – everyone knew this. Moreover, the AWP for a generic drug is a price that is a market entry requirement. (*Id*. at ¶¶ 88-89.) Without an AWP at least 10% below the generic drug, the generic drug will not appear in industry compendia as a generic drug. (Dkt. 6190 at ¶¶ 66-70.) The Government's case paints a false picture of the market for Medicare drugs. The Government would have the jury believe that Dey knew – and indeed, the whole industry believed – that AWP was intended to represent a net discounted average of prices paid by retailers to wholesalers, *i.e.*, that they represented "actual prices in the market", and Dey, therefore, allegedly defrauded the Government by publishing AWPs that were significantly higher than the net discounted average prices that existed in the market. In fact, this premise is completely false as the OIG reports demonstrate. The OIG reports accurately portray: (i) no drug

manufacturer's AWP was a transaction price; (ii) the market and CMS understood AWP exceeded transaction price; and (iii) the Government considered alternatives to AWP such as actual acquisition cost but decided not to use it. This government knowledge evidence directly refutes what the Government claims. For instance, the February 1996 OIG Report, "Medicare Payments for Nebulizer Drugs," which included a study of albuterol sulfate, observes that AWP levels exceed the prices that pharmacies actually pay. (*See* Dkt. 6184, Ex. 47, at 6-8.) The OIG recommends multiple solutions – none of which faults drug manufacturers: (i) discount AWP like Medicaid, (ii) implement a rebate program, (iii) competitive bidding, and (iv) have DMERC use "actual acquisition cost". (*Id*. at 11-12.) Simply reviewing these alternatives confirms that no one believed AWP was a net discounted average of prices.

The Government also argues that permitting government knowledge evidence on the question of falsity would invite the jury to reach a finding contrary to the holdings of this Court and the First Circuit (the "MDL Class cases"). (Pl. Mem. at 4.) The Government relies on a quote taken out of context from the First Circuit opinion regarding Congress' intentions. (Pl. Mem. at 2.) This Court and the First Circuit did not decide the MDL Class cases on Congress' intentions, but instead made a specific holding under the Massachusetts Consumer Protection Act regarding private third party-payor expectations about the relationship between published AWPs and acquisition costs for single-source drugs. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 39-41, 76-78, 86-92 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 171-72, 178-84 (1st Cir. 2009) ("*AstraZeneca*"); *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 231, 236-37 (1st Cir. 2009). As the First Circuit held:

> [T]he 30% trigger represents not a per se threshold for liability based on the violation of a separate legal duty, but instead, as is

> clear from the intensely factual nature of Dr. Hartman's report and the district court's June 2007 order, constitutes a specific factual conclusion about what conduct in this case would trigger potential liability under Chapter 93A as to these plaintiffs based on the TPPs' actual commercial expectations.

AstraZeneca, 582 F.3d at 183.[3]

The MDL Class cases were not FCA cases, nor did they base liability on a "plain meaning" interpretation of AWP in the 1997 Balanced Budget Act ("BBA"), but rather on third-party payors' commercial expectations. Prior to enactment of the BBA, the First Circuit agreed that AWP was an "unsettled" term. *AstraZeneca*, 582 F.3d at 169-70. Additionally, it certainly would be relevant in this case for this Court and the First Circuit to learn that even after 1998, CMS continued to direct its DMERCs to use compendia AWPs as opposed to plain meaning AWPs, despite knowing the clear difference between the two.

The United States was not a party to the MDL Class cases and invoked the *Touhy* regulations to shield itself from discovery. By contrast, in this action, discovery and the evidentiary record demonstrating the Government's knowledge is far more extensive. For the first time the fact-finder will have the opportunity to hear from CMS – as opposed to DOJ attorneys – just what CMS understood AWP to be. This motion is merely another thinly-veiled attempt to continue to prevent the whole record from being heard. The government knowledge evidence will demonstrate that the Government knew of the generics spreads but encouraged them because even with those spreads, generics represented an enormous savings for Medicare. (*See* Dkt. 6429 (Combined Memorandum of Defendants in Opposition to the United States'

[3] Moreover, the 30% test was based on an analysis of the relationship between AWP and WAC for single-source drugs by Dr. Raymond Hartman, plaintiffs' expert on behalf of the purported private class action in the MDL Class Case. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 86. Dr. Hartman testified there is no economic study or basis for concluding that there is a similar fixed relationship between the WAC and AWP of a generic drug. (Reid Decl., Ex. 3 at 328:7-13, 430:15-432:16.)

Cross-Motions for Partial Summary Judgment) at 2-3, 11-15; Dkt. 6447 ¶¶ 1-3, 9, 11, 13, 95-96, 98-104; Dkt. 6190 ¶¶ 60-61.)[4]

E. Government Knowledge Is Relevant to "Scienter"

The Government's motion should be denied because "[i]t is well settled that the Federal government's knowledge of an alleged 'false' claim contradicts a defendant's intent to knowingly submitted [sic] a false claim." *Englund*, 2006 WL 3097941, at *12 (granting summary judgment for defendant where the state and federal officials were aware of the allegedly "false" nature of the claims); *see also Mylan Labs.*, 608 F. Supp. 2d at 149 (holding that government knowledge can negate the scienter element "when the government's knowledge [of the defendant's] actions is so *extensive* that the defendant could not as a matter of law possess the requisite state of mind to be liable under the FCA"). In other words, without an opportunity to weigh the government knowledge evidence, the jury cannot properly determine whether the Government has met its burden of proving scienter. The defendant need not be aware of the Government's knowledge. *See Englund*, 2006 WL 3097941, at *13-14. For example, in *Englund*, the court relied on government knowledge evidence relating to what CMS knew based on the testimony of former Administrator, Thomas Scully – just as Dey does in this case. *See id*. The court further relied on widespread knowledge of the "scheme" derived from congressional hearings. *See id*. at *14-15. The court did not, however, consider whether the defendant relied on any of this information when submitting the allegedly false claims. *See id*. at *13-15.

[4] The Government's reliance on *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), is misplaced because *Lachman* is not an FCA case. Moreover, *Lachman* itself recognized that, "[w]hen the agency itself issues contradictory or misleading public interpretations of a regulation, there may be sufficient confusion for a regulated party to justifiably claim a deprivation of fair notice." 387 F.3d at 57. Also, *United States ex rel Oliver v. Parsons Co.*, 195 F.3d 457 (9th Cir. 1999), is inapposite because the holding rested on an interpretation of technical federal accounting regulations that governed what costs the defendant contractor could bill to the government. *Id.* at 462-63. Here, by contrast, there is no definition of AWP in any statute or regulation.

Presumably, the Government seeks to preclude Dey from presenting evidence from senior federal officials – such as former Administrator Thomas Scully – and official government reports, many of which relate specifically to Dey's drugs. This evidence shows the Government's knowledge that published AWPs for generic drugs bore no predictable relationship to the final net prices providers paid to acquire those drugs and that reimbursement payments based on AWP were significantly higher than providers' actual costs to acquire drugs. For example, in 1997, the OIG issued the results of a survey of thousands of invoices for generic drugs gathered from hundreds of pharmacies from across the country in a report entitled "Medicaid Pharmacy –Actual Acquisition Cost of Generic Prescription Drug Products." (*See* Dkt. 6449, Ex. 50.) The report concluded that pharmacies could purchase the top 200 generic drugs as measured by Medicaid reimbursement payments for an average of 42.5 percent below the published AWPs for those drugs. (*Id*. at 4.) Meanwhile, starting in 1996, the OIG began publishing reports specifically about Dey's drugs and finding the precise difference between AWP and the invoice price for Dey's drugs. (*See* Dkt. 6190 at ¶¶ 117-31.) Additionally, during his deposition, Robert Niemann – a former CMS employee described by other CMS and OIG employees as "knowledgeable", the "point person on drugs" and "the single largest source of information about AWP" – testified as follows:

> Q. And just so we're clear, when I used the term average wholesale price in my question what do you understand me to mean?
>
> A. The way it's used in the industry.
>
> Q. Which is how?
>
> A. Drug companies assign a sticker price to their drugs that are published in compendia like the Red Book. ***In other words, I assumed that you weren't using the word average, wholesale, price, but rather the term of art.***

(Reid Decl., Ex. 5 at 601:12-21 (emphasis added); Ex. 6 at 163:16-164:1; Ex. 7 at 456:9-15; Ex. 1 at 126:16-18, 150:15-17.)

The government knowledge evidence described above, and the vast amount of similar evidence (*see* Dkt. 6429 at 2-3, 8-9, 11-13; Dkt. 6447 ¶¶ 1-3, 9, 11, 13, 37, 95-96, 98-104) demonstrates that no one in the pharmaceutical industry – including the government officials responsible for administering the Medicare program – had any understanding that AWPs were meant to approximate the providers' net discounted cost to acquire Dey's drugs or any other generic drugs. This evidence of industry-wide understandings is properly admissible to rebut Plaintiffs' claim that Dey "knowingly" made a false statement or record or "knowingly" caused the submission of a false claim by reporting AWPs that did not reflect providers' actual net costs. *See Englund*, 2006 WL 3097941, at *14-15.[5]

Additionally, it appears that the Government may explicitly or implicitly tell the jury that, generally, drug manufacturers report "true" AWPs, and only Dey, and perhaps Roxane, allegedly reported "false" AWPs. Plaintiffs' expert, Dr. Mark G. Duggan, assumed for his analysis that the AWPs of drug manufacturers other than Dey and Roxane are "true" because only Dey and Roxane had been sued by the DOJ. (*See* Dkt. 6184, Ex. 291 at 434:1-7.) The notion that the AWPs for Dey's generic drugs were outliers as compared to other generic drug

[5] The cases cited by the Government are inapposite because they do not concern the relevancy of government knowledge evidence of an industry-wide understanding of a term or an alleged industry-wide scheme to defraud. *See United States v. Lussier*, 929 F.2d 25 (1st Cir. 1990); *United States v. St. Pierre*, 599 F.3d 19 (1st Cir. 2010); *United States ex rel. Irwin v. Significant Educ., Inc.*, No. CV-07-1771-PHX-DGC, 2009 WL 322875, at *2 (D. Ariz. Feb. 10, 2009). The Government's reliance on *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp.2d 539, 562-63, n. 29 (E.D. Va. 2003) is also misplaced because the court found that "this history of agency and industry dispute and doubt over the proper interpretation and application of the [relevant regulations] points persuasively away from a conclusion that [the defendant] must have known, at any time between 1994 and 1999, that its general … charging practices were in violation of the [relevant regulation]."

manufacturers is preposterous. The Medicare arrays, themselves, will show several generic manufacturers with similar or even higher AWPs. *See also, e.g.*, 1997 OIG Report, "Excessive Medicare Payment For Prescription Drugs", (Dkt. 6184, Ex. 50) (finding that "[t]he published AWPs [] bear little or no resemblance to actual wholesale prices…." for the top 22 Medicare drugs). Government knowledge evidence should, therefore, also be permitted to counter any such explicit or implicit contention by the Government that Dey acted wrongfully because it acted inconsistently with the conduct of other generic drug manufacturers.

F. Government Knowledge Is Relevant to Causation

To establish liability under the FCA, Plaintiffs must show that Dey "cause[d] to be presented, to an officer or employee of the United States Government … a false or fraudulent claim for payment or approval …" or "cause[d] to be made or used, a false record or statement to get a *false or fraudulent claim* paid or approved by the Government …." *See* 31 U.S.C. § 3729(a). Where there is nothing false about the claims themselves, and the only purported falsity about the claim is the rate that the Government itself chose to pay, then evidence relating to what the Government believed it was paying and intended to pay is relevant to determine whether the Government paid an amount contrary to its intention and belief.

Government knowledge evidence, *i.e.*, evidence relating to the Government's knowledge and intentions, therefore, is precisely the type of evidence that a fact-finder would need to evaluate. This is particularly true where, as here, the Government not only understood that Medicare claims paid based on median AWP arrays exceeded providers' actual costs, but did not define AWP in any statute or regulation to provide drug manufacturers any guidance as to how that figure should be calculated. The government knowledge evidence that the Government seeks to exclude will show that the responsible government officials and agencies deliberately adopted a reimbursement system that they knew would pay providers at significantly

more than their net discounted costs for the drug ingredient cost portion of reimbursement. The Government contends that this would be illogical, but the government knowledge evidence the Government seeks to exclude would demonstrate why it made sense for the Government to do so. For example, the evidence demonstrates that the payment for the cost of the drug was used to cross-subsidize low and otherwise unreasonable dispensing fees, that Medicare intentionally gave providers a financial incentive to participate in the program, and that politics played a role in any proposed rate reduction. (*See* Dkt. 6447 ¶¶ 112-125, 134-49.)

The Government's argument on causation also fails because it is based on the inherently flawed premise that Dey set the AWPs used by Medicare for calculating reimbursement to induce customers to purchase its drugs. (Pl. Mem. at 6.) This is a complete mischaracterization of the reimbursement system under Medicare and ignores the plain and simple fact that drug companies cannot "market the spread" on generic drugs in the Medicare system. Medicare reimbursement for generic drugs is based on a median AWP set by the Medicare DMERCs under CMS guidance and supervision. The median is created by an array of selected AWPs after looking at the AWPs from all drug manufacturers for the therapeutically-equivalent drugs. Dey had no power to set the median AWP because it had no power to set the AWPs reported by other drug manufacturers. Moreover, since a median AWP is used, a generic drug manufacturer cannot "market the spread" between its AWP and the net acquisition cost to entice Medicare providers to purchase its drugs, since its AWP is not the basis for reimbursement and all providers are paid the same amount regardless of which manufacturer's drug is dispensed. In other words, there is no differential spread to market in Medicare.

III. EVIDENCE RELATING TO THE CHANGE IN DISPENSING FEES IS ADMISSIBLE

The Government's final argument is aimed at preventing Dey from presenting

evidence of cross-subsidization; specifically, evidence relating to the Government's decision to increase dispensing fees in 2004. Strictly speaking, this is not an argument about government knowledge evidence; that is, it is not evidence of what the Government knew, but of what the Government did. Regardless of how the Government characterizes it, this Court has already ruled that evidence of cross-subsidization is admissible. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F.Supp.2d at 32, 37-38. At the bench trial of the MDL class case, the Court held that the defendants failed to present sufficient evidence that "any margin over the 20 to 25 percent industry-wide formula was needed to compensate doctors for their costs of administration for these drugs and risks like spoilage." *See id*. at 37-38. Dey should be permitted the opportunity to present that evidence in its trial.

Moreover, this evidence is directly relevant to the Government's allegation that it overpaid for the Dey drugs. "[T]he measure of the government's damages under the False Claims Act would be the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful." *See Coleman v. Hernandez*, 490 F. Supp.2d 278, 281 (D. Conn. 2007). When the government pays on a false claim, but nonetheless receives something of value, the measure of damages is the difference between what the government paid and the value of what the government received. *See id*. at 282.

In this case, since there is no dispute that the providers actually dispensed the drugs for the reimbursement claims in question, the measure of any alleged damages would be the difference between what the government paid on those claims and the total value of the services provided. The best evidence of what the Government would have paid had it been using a net discounted average price is evidence of what the Government did pay when it changed the reimbursement methodology to start using a net discounted average price. The Medicare

Prescription Drug, Improvement and Modernization Act ("MMA") revised the Medicare reimbursement formula from one based on AWP to one based on ASP. *See* 42 U.S.C. 1395w-3a (b)(1). ASP is defined by statute as an actual average of the prices charged by manufacturers to all purchasers of a drug, net of all discounts. *See id*. at (c). At the same time, the dispensing fee paid for dispensing inhalation drugs such as the Dey subject drugs was raised dramatically, from $5 to first $57 and then ultimately to $33. (*See* Dkt. 6449, Ex. 212 (70 Fed. Reg. 70116, 70225 (Nov. 21, 2005)).) The MMA demonstrates how much the Government would have increased the dispensing fee portion to offset the ingredient cost portion of the payment methodology.

The Government contends that evidence concerning the Medicare payment rates for inhalation drugs following the enactment of the MMA are inadmissible because they post-date the relevant time period and applying them to calculate damages would be speculative. The post-MMA payment rates are not speculative; they are rates that Medicare actually paid. Also, the Government itself concedes that "*de facto* cross-subsidization" was occurring and that a goal of the MMA was "to eliminate cross subsidization of services." (Pl. Mem. at 15 (quoting 69 Fed. Reg. 66236, 66320 (Nov. 15, 2004)).) If margins from AWP-based ingredient reimbursements were off-setting or "cross-subsidizing" dispensing fee shortfalls prior to the passage of the MMA, and the MMA was intended to correct for that cross-subsidization and pay providers for their actual costs to dispense, then the MMA payment rates speak directly to the value of the services being provided pre-MMA.

Moreover, evidence in the record corroborates that Medicare would have taken similar steps to offset the loss of the margin providers received from AWP payments, if in fact the Medicare program used net discounted prices as a basis for reimbursement during the relevant time period. For instance, in December 1995, when CMS contemplated moving by

regulation from AWP to actual acquisition cost ("AAC"), they proposed adding a dispensing fee to account for the services provided by the pharmacy. Robert Niemann, a former policy analyst who CMS employees described as the Medicare payment policy expert during the relevant period, testified as to the draft regulation:

> Q. Would you agree with me that that addition of a dispensing fee was intended to account for the loss of margin to these providers in going from an AWP system to an AAC system?
>
> A. Yes. I think that's right.

(Reid Decl., Ex. 4 at 284:17-22; *see also* Ex. 8.)

Apparently assigning itself the role of Plaintiff, judge and jury, the Government makes the unusual argument that Dey should not be permitted to present evidence of cross-subsidization because there is no evidence of cross-subsidization. It is for the jury to make a finding of fact on cross-subsidization, not the Government.[6] The Government is free to make its arguments at trial, but both sides should be permitted to present evidence to the jury to support their arguments so that the fact-finder has the complete record on which to decide these claims.[7]

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[6] Ironically, in support of its position, the Government points to evidence that shows that from as early as 1991, the DME payment was used to cross-subsidize the dispensing cost of the drug. When the rental allowance was discontinued, a new HCPCS code was instituted to cover the nebulizer drug dispensing costs. However, the $5 dispensing fee was inadequate to cover all of the dispensing costs, and thus providers relied upon the spread built into the AWP reimbursement system. The reason why the dispensing fee was raised when Medicare switched from AWP to ASP was to ensure adequate payment for dispensing costs that would no longer be covered by the AWP spread. (*See* Reid Decl., Ex. 4 at 284:17-22.) Indeed, the dispensing fee is tied to the dispensing of the drug, not the rental of DME.

[7] Plaintiffs' reliance on *Ward v. Dixie Nat'l Life Ins. Co.*, 595 F.3d 164 (4th Cir. 2010) is misplaced. *Ward* involved a breach of an insurance contract, not an FCA claim, and the court's analysis hinges on the benefit of the bargain concept of contract law. The court made no ruling on the admissibility of the evidence in question. Moreover, in that case, there was no indication that plaintiff insureds ever actually paid the higher premium rates that defendants argued offset their damages. Here, by contrast, there is no speculation as to whether the government would have paid post-MMA rates: it did pay them and continues to pay them today.

CONCLUSION

For the reasons set forth herein, this Court should deny the United States' Motion in Limine to Preclude Evidence of Government Knowledge.

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Respectfully Submitted,

KELLEY DRYE & WARREN LLP

By: /s/ Sarah L. Reid
Paul F. Doyle (BBO # 133460)
Sarah L. Reid *(pro hac vice)*
William A. Escobar *(pro hac vice)*
Neil Merkl *(pro hac vice)*
101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Martin F. Murphy, BBO #363250
Robert E. Toone, BBO #663249
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210
Telephone: (617) 832-1000

Attorneys for Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on July 14, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Sarah L. Reid
Sarah L. Reid